IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2326

THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Thomas H. Barker, Ph.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Defendant's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. filed by Boston Scientific Corporation ("BSC"). [ECF No. 4820]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, BSC's Motion is **GRANTED**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the BSC MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, http://www.wvsd.uscourts.gov/MDL/boston/orders.html. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v.*

Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We

agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Barker is an Associate Professor at the Georgia Institute of Technology, where he teaches courses in biomedical engineering, cellular and molecular biology, advanced biomaterials, and cellular and molecular bioengineering. He has a Ph.D. in biomedical engineering.

A. Mechanical Mismatch Between Mesh and the Human Body

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding six to seven kilopascals for vaginal tissue. However, he admits that he has no

scientific basis for forming a kilopascal number for BSC mesh. Moreover, Dr. Barker admits that, although "[t]here's significant evidence in the medical literature that there are regimes that the mesh is not mechanically matched with vaginal tissue . . . the studies were never done, so we can't say for sure." Barker Dep. (Dec. 15, 2014) [ECF No. 4820-6], at 108:10–22). He also testifies that "there's certainly data to suggest that the mesh gets significantly stiff under load" but then concedes that, "without proper testing, it's everyone's guess." *Id.* at 111:13–14. Such an opinion rests on an unreliable basis and is therefore unreliable. Additionally, to the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Accordingly, Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**. BSC's Motion is **GRANTED** on this point.

B. Clinical Significance of the Mechanical Mismatch Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are unreliable as well. His opinion on the mechanical mismatch generally is unreliable, and, thus, any derivative opinions of such are also unreliable. Dr. Barker testified that testing would need to be done in order to determine the effect that an implant may have *in vivo*. However, he also stated that no one has performed this testing for transvaginal mesh. Concluding that mesh degrades, deforms, or causes scarring in the human body based on speculation that there is a mechanical mismatch between vaginal tissue and BSC mesh fails to survive *Daubert* scrutiny. Moreover, in forming these *in vivo* opinions,

Dr. Barker relied on a mesh study performed *ex vivo*, where the authors explicitly state that their study does not conclusively reveal the mesh's behavior in the human body. *See* Shepard, JP et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes for Pelvic Organ Prolapse*, 23 Int'l Urogynecology J. 613, 619 (2012) (stating that "the experimental setup allows us to draw only preliminary conclusions about the various meshes"). Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately thirty-five to fifty-two percent deformation in its mesh samples. Dr. Barker bases this opinion on a BSC email. However, when questioned about this topic, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. This deposition testimony further reveals the unreliability of Dr. Barker's methodology. Therefore, Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue are **EXCLUDED**. BSC's Motion on this point is **GRANTED**.

IV. Conclusion

To summarize, BSC's *Daubert* Motion concerning Dr. Barker [ECF No. 4820] is **GRANTED**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Number	Case Name
2:17-cv-02202	Atwood v. Boston Scientific Corporation